CHEMATIC® CLEANERS

Our cleaning science gets you back to business faster
Equipment cleaning after processing EUDRAGIT® RL/RS, EUDRAGIT® NE/NM and EUDRAGIT® L, FS & S formulations is now an efficient and safe process.

Special detergents have been developed by Dober, USA, in close cooperation with Evonik.

Chematic® Cleaners provide optimized cleaning results with minimum efforts.

Chematic® Cleaners take advantage of a special detergent system which aids in the removal of both the EUDRAGIT® polymers and associated excipients.

Evonik and Dober have a strategic partnership combining Evonik’s know-how in functional polymers and drug delivery systems with Dober’s unique approach to cleaning science.

CHEMATIC® CLEANERS

Achieve significant time and cost savings by using Chematic® for effective cleaning processes.
CLEAR VIEW ON THE ADVANTAGES

Chematic® Cleaners can be applied for manual WIP and CIP processes. Due to their mild chemistry and low process temperatures they are highly suitable for manual cleaning procedures as well.

SAFETY
• Minimized need for operator intervention
• Not irritating
• High compliance by personnel
• Reduced disassembly
• No solvent usage and exposure

EFFICIENCY
• Cleaning time reduced by more than 65%
• Energy savings of about 70%
• Equipment down time minimized
• Reduced labor costs
• Simplified procedures

RELIABILITY
• Consistent results
• GMP compliant
• Robust cleaning process
PRODUCT OFFERINGS

Our cleaning science gets you back to business faster, automatically!

**EUDRAGIT® L, FS & S-polymer**
- enteric
- challenging

Detergent:
- Chematic® L/S

**EUDRAGIT® NE- & NM-polymer**
- pH-independently insoluble and permeable
- challenging

Detergent:
- Chematic® NE/NM

**EUDRAGIT® E-polymer**
- taste masking and protective coating

Detergent:
- contact Evonik for a specific solution

**EUDRAGIT® RL- & RS-polymer**
- pH-independently insoluble and permeable
- challenging

Detergent:
- Chematic® RL/RS

*Pigmented formulations*
CLEANING EFFICIENCY

The optimal combination of Time, Action, Chemistry and Temperature in all Chematic® Cleaners provides best in class cleaning results.

**Less Time**
- No scrubbing, less cleaning cycles
- No haze from TiO$_2$ or iron oxides

**Less Action**
- Automated WIP / CIP processes

**Mild Chemistry**
- Optimized for EUDRAGIT® polymers
- Cost savings
- Regulatory compliant

**Low Temperature**
- Cleaning at temperatures below 50 °C
- Applicable for manual processes
# APPLICATIONS

<table>
<thead>
<tr>
<th>EUDRAGIT® polymers</th>
<th>CHEMATIC® RL/RS CLEANER</th>
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<tbody>
<tr>
<td></td>
<td>EUDRAGIT® RL 100 EUDRAGIT® RS 100</td>
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<tr>
<td></td>
<td>EUDRAGIT® RL 30 D EUDRAGIT® RS 30 D</td>
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<table>
<thead>
<tr>
<th>Recommended process parameters</th>
<th>CHEMATIC® RL/RS CLEANER</th>
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<tbody>
<tr>
<td>WIP / CIP</td>
<td>Cold water pre-rinse, 20 °C</td>
</tr>
<tr>
<td>Manually</td>
<td>4 – 8 % v/v 50 – 60 °C</td>
</tr>
<tr>
<td>Physico-chemical properties</td>
<td>Transparent, water-white liquid</td>
</tr>
<tr>
<td>pH (v/v solution)</td>
<td></td>
</tr>
<tr>
<td>CHEMATIC® NE/NM CLEANER</td>
<td>CHEMATIC® L/S CLEANER</td>
</tr>
<tr>
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<tr>
<td>EUDRAGIT® NE 30 D</td>
<td>EUDRAGIT® L 100-55</td>
</tr>
<tr>
<td>EUDRAGIT® NE 40 D</td>
<td>EUDRAGIT® L 30 D-55</td>
</tr>
<tr>
<td>EUDRAGIT® NM 30 D</td>
<td>EUDRAGIT® S 100</td>
</tr>
<tr>
<td>EUDRAGIT® L 100</td>
<td>EUDRAGIT® S 12,5</td>
</tr>
<tr>
<td>EUDRAGIT® L 30 D-55</td>
<td>EUDRAGIT® FS 30 D</td>
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**Application concentration/temperature**

<table>
<thead>
<tr>
<th></th>
<th>CHEMATIC® NE/NM CLEANER</th>
<th>CHEMATIC® L/S CLEANER</th>
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<tbody>
<tr>
<td><strong>4 – 8 % v/v</strong></td>
<td>Cold water pre-rinse,</td>
<td>2 – 6 % v/v post-rinse,</td>
</tr>
<tr>
<td><strong>50 – 60°C</strong></td>
<td>20–30°C</td>
<td>50–60°C</td>
</tr>
<tr>
<td></td>
<td>Cold water pre-rinse,</td>
<td>4 – 6 % v/v post-rinse,</td>
</tr>
<tr>
<td></td>
<td>20–30°C</td>
<td>20–50°C</td>
</tr>
<tr>
<td></td>
<td>Transparent, amber liquid</td>
<td>Clear, light yellow to amber liquid</td>
</tr>
<tr>
<td>(10 % v/v solution)</td>
<td>11.0 – 12.0</td>
<td>(6 % v/v solution) 16.60 – 11.60</td>
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CASE STUDY

EUDRAGIT® NE 30 D

- Coating Pan (60 inch O’Hara)
- One production run, soil sat 24 hours

ORIGINAL PROCESS:
- Labor intensive; resulting in ergonomic issues
- Residue peels off & blocks perforations
- Inconsistent cleaning impacts scheduling

Manual cleaning: 2–6 hours
WIP/CIP cleaning: 2 hours

GOALS OF NEW PROCESS:
- Improve operator safety
- Decrease manual labor
- Allow for more consistent cleaning process using CIP
- Reduce clean time

RESULTS:
- Chematic® NE/NM Cleaner

Manual cleaning: 15–30 minutes
WIP/CIP cleaning: ~2 hours

BENEFITS:
- Safer process for operators
- Less manual labor intensive process
- Detergent dissolves residue
- Significant time and cost savings
- Consistent cleaning process allows improved scheduling
- Improved capacity
After cleaning

EUDRAGIT® RS 30 D

• Fluid Bed (Glatt WSG 200 with 46 inch Wurster)
• Multiple batches

ORIGINAL PROCESS:
• Labor intensive; manual process involves power washing, hand scrubbing & disassembly
• Complicated cleaning procedure with hazardous detergents

Manual cleaning: 24 hours

GOALS OF NEW PROCESS:
• Improve safety
• Decrease manual labor
• Eliminate scrubbing by using chemical spray wands
• Less complex process
• Reduce down time

RESULTS:
• Chematic® RL/RS Cleaner

Manual cleaning: 4 hours

BENEFITS:
• Safety improved
• Manual labor significantly reduced, no scrubbing
• Greatly reduced clean time by robust cleaning process
• Increased capacity
• Reduced labor costs
• Significant time and cost savings
EUDRAGIT® L Series

- Coating Pan (Glatt GMPC II (75 cm))
- One production run, soil at 40% solids

ORIGINAL PROCESS:
- Labor intensive; resulting in ergonomic issues
- Polymer dissolves completely but pigments settle back
- Haze visible on surface
- Re-cleaning was required due to haze

Manual cleaning: 2–6 hours
WIP/CIP cleaning: 30 minutes–2 hours

GOALS OF NEW PROCESS:
- Decrease manual labor
- Eliminate scrubbing
- No haze from TiO₂ or Iron Oxides or Talc
- Reduce cleaning time

RESULTS:
- Chematic® L/S Cleaner

Manual cleaning: 0–30 minutes
WIP/CIP cleaning: 1 hour

BENEFITS:
- No manual scrubbing
- No haze from TiO₂ or Iron Oxides or Talc post cleaning
- Pigments best removed with cold pre and post rinse
- Significant time and cost savings
- Consistent cleaning process allows improved scheduling
- Improved capacity
OUR SERVICE OFFERINGS FOR YOUR CLEANING OPTIMIZATION

Combining the deep formulation and process understanding of Evonik with the high cleaning expertise of Dober we offer technical and regulatory support to ensure both fast and effective cleaning as well as processes and documentation accepted by the authorities.

<table>
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<tr>
<th>Basic support</th>
<th>Standard service</th>
<th>Regulatory support</th>
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<tr>
<td>1 L samples with standard recommendations</td>
<td>Information exchange</td>
<td>ACM study</td>
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<tr>
<td>Requirements and needs</td>
<td>Optimization trials at Evonik/Dober</td>
<td>Cleaning report</td>
</tr>
<tr>
<td>Process description</td>
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WATCH CHEMATIC® RL/RS CLEANER PERFORM IN REAL TIME:
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EUDRAGIT = reg. trademark of Evonik Industries AG and its subsidiaries

CHEMATIC = reg. trademark of Dober, Woodridge, IL, USA